K021421

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510(k) SUMMARY of Safety and Effectiveness

(Persuant to 21 CFR 807.92)

APR 1 8 2003

I. GENERAL

A.	**Submitted By**:	TZ Medical Inc. 7272 S.W. Durham Road #800 Portland, Oregon 97724
B.	**Contact Person**	Madalyn C. Duncan Regulatory Specialist
C.	**Proprietary Name**:	PadTac Electrophysiology Recording Catheters PadTac Junction Cable Connector PadTac Cable
D.	**Classification Name**:	Electrode Recording Catheter
E.	**Classification:**	Class II, Cardiovascular DRF, CFR 870.1220

II. DEVICE INFORMATION SUMMARY

A.	**Predicate Device**	IBI 1100 Electrophysiology Catheter System K961924 IBI 1000 Electrophysiology Catheter System K946333
C.	**Device Description**	The PadTac Electrophysiology catheters are between 5 and 8 french (fr), 4, 10, 12 and 14 pole, fixed, monitoring and recording. The multi-electrode electrophysiology catheters are used for electrophysiology electrocardiograph recording and cardiac stimulation during diagnostic procedures. The cables and box serve as an extension between the catheter and the pin block.

B. Device Intended Use

The fixed PadTac electrophysiology mapping and recording catheters and PadTac cables are used for recording intracardiac electrogram (EGM) and for cardiac stimulation during diagnostic electrophysiology studies. The catheters will be used in the high right atrium, right ventricular apex and HIS bundle (recording only). The cables and box connect the catheter to the recording system.

III. SUBSTANTIAL EQUIVQALENCE TESTING SUMMARY

The TZ Medical PadTac EP Catheters have been tested and are considered safe and effective per "Electrode Recording Catheter Preliminary Guidance", Mark Massi, Pacing and Electrophysiology Device Branch, Division of Cardiovascular, Respiratory and Neurological Devices, Office of Device Evaluation FDA,CDRH, 1995.

The TZ medical PadTac cables have been tested and are considered safe and effective per "Standard for Medical Equipment; Part 1: General Requirements, UL 2601 (IEC 60601-1).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 8 2003

TZ Medical Inc.
c/o Ms. Madalyn C. Duncan
RA/QA Specialist
7272 S.W. Durham Rd., #800
Portland, OR 97224

Re: K021421
Trade Name: PadTac Electrophysiology Recording Catheters, Junction Box Cable Connector, and Electrophysiology Connector Cables
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode Recording Catheter
Regulatory Class: Class II (two)
Product Code: DRF
Dated: January 17, 2003
Received: January 21, 2003

Dear Ms. Duncan:

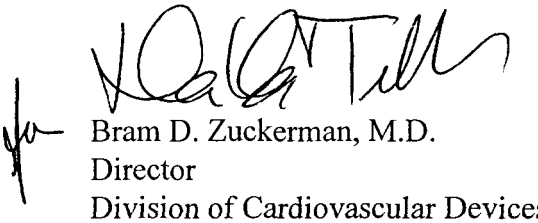
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known) K021421

Device Name: **PadTac Mapping and Recording EP Catheters:**

Indications for Use:

The fixed PadTac electrophysiology mapping and recording catheters and PadTac cables are used for recording intracardiac electrogram (EGM) and for cardiac stimulation during diagnostic electrophysiology studies. The catheters will be used in the high right atrium, right ventricular apex and HIS bundle (recording only). The cables and box connect the catheter to the recording system.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence Of CDRH, Office OF Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

Over-The-Counter Use_____

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K021421